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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,871	07/31/2003	Sharon Mi Lyn Tan	03-044	1798

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EXAMINER

YEBASSA, DESTA LETTA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/631,871

Applicant(s)

TAN, SHARON MI LYN

Examiner

Desta L. Yebassa

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 02/07/2005; 1/20/04.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

Acknowledgment is made for the information disclosure statement (IDS) filed 02/07/2005. Receipt also acknowledged of the oath or declaration filed on 07/31/2003.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-2, 5, 7-9, and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Solomon et al. (U.S. Patent No. 5,451,424).

Claims are generally directed medical article comprises antimicrobial agents. Claim 5 is depends from claim 4, which in turn depends from claim 3. Claims 2 and 3 are depending from claim 1. Solomon et al. discloses medical articles comprising of antimicrobial agents, including antibiotics such as penicillin, antiviral agents, and the like which inhibit or reduce bacterial growth (abstract and column 2, lines 40-55). Solomon et al. also disclose typical examples of medical articles including catheter, such as urinary catheters, drainage bags, abdominal cavity drainage, drainage tube, and any medical article compatible with chlorhexidine (column 4, lines 1-10 and column 7 through 8 example 1). Claims 1, 2 and 5 are clearly anticipated by Solomon et al. Claims 7-9 and 18 are depending from claim 1. Claim 20 is depends from claim 19 which in turn depends from claim 1. Solomon et al. disclose method and process for

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preparing antimicrobial or anti-infective medical articles comprising of a polymer core and layer such as polyurethans, siloxane urethane, and copolymers (column 2, lines 40-55 column 3, lines 5-25 and 55-60, column 4, 1-25 and column 5, lines 50-65).

Therefore, claims 7-9, and 18-20 are clearly anticipated by Solomon et al.

2. Claims 1-2 and 7-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Umemura et al. (U.S. Patent No. 4,902503).

Claim 2 is depends from claim 1. Umemura et al disclose antimicrobial agent and latex composition comprising of natural and synthetic polymer latex. (abstract column 2, lines 40-55 ). Umemura et al also disclose antimicrobial latex products include various catheters such as urine catheters, bags such as stercus bags, drainage, tubes, sponges, rubrerized fabrics such as bed sheets, and diaper covers, and the like (column 5, lines 35-40). Claims 1-2 are clearly anticipated by Umemura et al. Claims 7-10 are depending from claim 1. Claim 11 depends from claim 10, which in turn depends from claim 1. Claims 12-17 are depending from claim 1. Umemura et al disclose Natural polymer rubber latex such as Sotex and Asiatex; Synthetic polymer latex includes homopolymers and copolymers for example, such as ethylene, styrene, methacrylate and the like various organic and inorganic materials including silver and silver compound include silver salts such as silver nitrate, silver chlorate and the like (column 3, lines 15-25 and 50-65 and column 4, lines 40-55). Therefore claims 7-17 is anticipated by Umemura et al.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Umemura et al. (U.S. Patent No. 4,902,503) in view of McGlothlin et al. U.S. Patent No. 6,329,444).

Umemura et al. has been discussed above.

Umemura et al. does not specifically teach a medical article with balloon catheter and antimicrobial region which is vulcanized.

McGlothlin et al disclose the preparation of synthetic rubber medical articles formed by dip-modeling synthetic polyisoprene that involves (dip-modeling, curing, vulcanization, and drying) suitable as substitutes for devices made of natural rubber (abstract, column 3, lines 40-50, column 4, lines 50-65 and column 5, lines 20).

McGlothlin et al also disclose polymer latex products include surgical gloves, catheter

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balloons, uterine ablation balloons, in-dwelling urinary drainage, and the like (column 45-50).

Therefore, it would have been obvious to one of ordinary skill in the art to use the antimicrobial agent and latex composition of Umemura et al. since McGlothlin et al disclose polymer latex medical article formed by dip-modeling synthetic polyisoprene that is suitable as substitutes for medical article or devices made of natural rubber, without any of the allergic reaction or other health problems. One of ordinary skill in the art would be motivated to combine the compositions taught by Umemura et al. and McGlothlin et al for the preparation of effective antimicrobial medical article in similar condition with a reasonable expectation of success. The prior art references, as combined teach the limitations of the instant claims. Therefore, the invention as whole has been prima face obvious to one of ordinary skill in the art at the time the invention was made.

### **Telephonic Inquiry**


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Desta L. Yebassa whose telephone number is 571-272-8511. The examiner can normally be reached on Monday to Friday 8.00 am –6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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